UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al*,**
Case No. 2:18-cv-1509

EVIDENTIARY MOTIONS OPINION AND ORDER NO. 10

This Opinion addresses the Defendants' Motion to Exclude the Opinion and Testimony of Plaintiff's Expert Jimmy Mays, Ph.D. (ECF No. 30). For the reasons that follow, Defendants' motion is **GRANTED IN PART AND DENIED IN PART**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.) This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020). The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k) process in 2010 and later

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25. Now, various evidentiary motions are ripe for adjudication.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an

evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharmaceuticals., Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting Fed. R. Evid. 702)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

> Expert testimony is admissible if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (citations omitted). Only the latter two steps are at issue here.

Dr. Mays is a materials scientist with an expertise in polymer science. (ECF No. 30 at PageID #791.) Defendants challenge his opinions related to the oxidative degradation of polypropylene in the body, biosorbable polymers, expanded poly(tetrafluoroethylene) ("ePTFE"), and poly(ethylene terephthalate) ("PTE"). (*Id.* at PageID #788.) Defendants argue that his opinions are irrelevant and unreliable, and that some opinions impermissibly summarize events and evaluate defendants' knowledge and state of mind. (*Id.* at 796–809.) Some, but not all, of Dr. Mays's opinions are irrelevant, unreliable, and address impermissible topics.

A. Relevance

Expert testimony must be relevant, meaning it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir.

2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); *see also* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Dr. Mays's general causation opinions and testimony are relevant to the extent that he discusses the degradation of polypropylene. His opinion that polypropylene degrades via oxidation in the body is consistent with Plaintiff's theory of injury in this case, which is that the ST coating of the Ventralight ST resorbed too quickly and that the exposure of bare polypropylene caused his adhesions. *E.g.*, *In re Davol, Inc./C.R. Bard, Inc.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *3 (S.D. Ohio Oct. 20, 2020). Thus, Dr. Mays's opinions fit the case because there is a "connection" between his testimony and "the disputed factual issues in the case." *Pride*, 218 F.3d at 578.

Defendants argue that Dr. Mays's opinions are irrelevant because there is no connection between degradation of polypropylene mesh in the body and adhesions, nor is there a connection between Dr. Mays's generic polypropylene opinions and the Ventralight ST. (ECF No. 30 at PageID #796–99.) In this Court's summary judgment opinion, it held that material questions of fact remained regarding whether *in vivo* oxidative degradation of polypropylene caused Plaintiff's

omental adhesions. *In re Davol, Inc.*, 2020 WL 5223363, at *13–14. And as this Court has explained before, an expert's opinions are not irrelevant because the expert "does not link them to Plaintiff's specific injuries." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *21 (S.D. Ohio Sept. 1, 2020). "A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536456, at * 2–3 (S.D.W. Va. Aug. 30, 2016) (denying motion to exclude expert's degradation and toxicity opinion despite expert's inability to connect them to plaintiffs' injuries because his testimony was "a relevant step towards establishing general causation."). Dr. Mays is not a specific-causation expert, so he need not provide the direct link to Plaintiff's injuries himself. He opines that polypropylene, a material that the Ventralight ST is made of, degrades oxidatively in the body, the mechanism that Plaintiff argues caused his adhesions. Accordingly, his opinions are relevant.

Some of Dr. Mays's opinions are irrelevant, however. Plaintiff references Dr. Mays's opinions regarding hernia recurrence, pain, and inflammation that is unrelated to the formation of adhesions (ECF No. 68 at PageID #3443–44), which are no longer viable injuries in this case, *In re Davol, Inc.*, 2020 WL 5223363, at *14. Plaintiff also concedes that any opinions related to cancer are not relevant to this case. (ECF No. 68 at PageID #3454.) Dr. Mays's opinions regarding ePTFE and PET are also irrelevant because these chemicals are present in "permanent composite meshes," such as the Composix Kugel, but do not appear to be in "partially resorbable composite meshes," which includes the Ventralight ST. (ECF No. 30-1 at PageID #819.) Plaintiff fails to address the relevance of ePTFE and PET in any manner.

B. Reliability

Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these factors "'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Daubert*, 509 U.S. at 594 (describing these factors as "flexible"). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Defendants raise four arguments regarding the reliability of Dr. Mays's opinions: (1) that Dr. Mays's opinions do not satisfy the requisite level of certainty, (2) that he failed to account for certain factors while forming his opinions, (3) that he based his opinion on statements in Material Safety Data Sheets ("MSDSs") for polypropylene resin, and (4) that he failed to independently validate Dr. El-Ghannam's findings in reaching his pre-implantation oxidative degradation opinion. Only Defendants' MSDS argument finds traction, however.

1. Requite level of certainty

The Sixth Circuit has remarked that "the majority of courts require that an expert opinion express a probability, which is more than a mere possibility." *Johnson v. Memphis Light Gas &*

Water Div., 695 F. App'x 131, 137 (6th Cir. 2017). But this is not a "'magic words' test." *Id.* at 136 (quoting *Thompson v. Underwood*, 407 F.2d 994, 997 (6th Cir. 1969)). "And the fact that an expert 'does not use absolute terms but rather couches the opinions in terms of "can" or "may" does not render it speculative or unreliable.'" *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 745 (N.D. Ohio 2011) (quoting *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489730, *8 (S.D. Fla. Mar. 19, 2010)). In other words, the district court must assess the whole of the expert's opinion, not isolated instances of word choice. Here, Dr. Mays's report is far from speculative—he opines that for a variety reasons and factors, polypropylene is capable of oxidative degradation *in vivo* and that this degradation will occur in the polypropylene present in Defendants' devices. (ECF No. 30-1 at PageID #820–21.)

Defendants point to a handful of instances of allegedly equivocal word choice in Dr. Mays's report (ECF No. 30 at PageID #799), but this is insufficient to render Dr. Mays's expert report speculative. For instance, Defendants' point to Dr. Mays's use of the word "susceptible" in his summary of his opinions (*id.*), but it Dr. Mays clearly concludes in the next few paragraphs "that all polypropylene hernia mesh implants will degrade *in vivo*" and that Defendants' mesh devices "are subject to oxidative degradation and will, foreseeably, degrade in the body when implanted as a permanent medical implant." (ECF No. 30-1 at PageID #820–21.) Defendants seek to disqualify expert opinions that contain words like "may," but this is simply a version of the "magic words" test that the Sixth Circuit forbids.

Defendants' position also finds no precedential support. In each decision cited, specific-causation experts were unable to conclude that an event was the probable cause of the plaintiff's injury. In *Davison v. Cole Sewell Corp.*, the Sixth Circuit held that the district court did not abuse its discretion when it excluded expert testimony in which the expert could only identify possible

proximate causes of injury—more than sixteen. 231 F. App'x 444, 450 (6th Cir. 2007); *see also Hutson v. Coviden Holding, Inc.*, No. 2:13-cv-895, 2015 WL 4040447, at *4 (S.D. Ohio June 30, 2015) (excluding expert testimony because the expert could not further rule out possible causes and opined that there were four possibilities of causation). Far from ruling in too many possibilities, Dr. Mays clearly concludes that oxidative degradation occurs.

2. Failure to evaluate certain factors

Next, Defendants argue that Dr. Mays's opinions are unreliable because he did not evaluate particular factors. (ECF No. 30 at PageID #801–03.) Defendants argue that Dr. Mays did not account for the induction period, *i.e.* the period before the polypropylene mesh oxidizes *in vivo*, or the degradation rate of Defendants' devices in Plaintiff or the other plaintiffs in this MDL, meaning that "Dr. Mays cannot rule out the possibility that Plaintiff's mesh was still within the induction period and did not have mesh degradation." (*Id.* at PageID #802.) Defendants also explain that because Dr. Mays did not provide a rate of degradation, he cannot determine to what degree of oxidative degradation occurred on Plaintiff's mesh. (*Id.*) And finally, Defendants contend that Dr. Mays did not "confirm[ ] that Plaintiff's Ventralight ST or any [of] Bard's hernia mesh contracted." (*Id.* at PageID #802–03.)

Defendants arguments are unpersuasive because they are iterations of Defendants' prior contention that Dr. Mays does not adequately tie his opinions to Plaintiff and his injuries, *i.e.* provide specific-causation opinions. As stated above, Dr. Mays's opinions as a general-causation expert are relevant and he is not required to supply every link in Plaintiff's chain of logic for his theory of the case. *Supra* Part III.A. Defendants can argue at trial that Plaintiff fails to demonstrate specific-causation, but Defendants' arguments do not address the reliability of Dr. Mays's expert report or testimony.

3. MSDS statements

Defendants assert that Dr. Mays's opinion that polypropylene is unsuitable for permanent implantation in the human body is unreliable because he relied on the MSDSs. (ECF No. 30 at PageID #807–08.) Defendants' emphasis on the MSDS is overblown, however. Dr. Mays relies on a variety other grounds throughout his report to reach his conclusion that polypropylene is unsuitable for permanent implantation, including his own research and ample scientific research. (ECF No. 30-1.) Dr. Mays's reliance on statements from MSDSs is insufficient to render his entire opinion unreliable.

Whether Dr. Mays may reference and rely on the MSDS in any manner in giving his opinions is another matter, however. Dr. Mays refers to the MSDS in two ways. First, he opines why the MSDS contained that statement and describes the information in the pertinent MSDSs. (ECF No. 30-1 at PageID #831–32.) Second, he refers to the MSDS statements that the polypropylene is unsuitable for permanent medical implantation. (*Id.* at PageID #820–21.) The Court concludes that he may not make these references.

Dr. Mays cannot opine on why a corporation included certain language in the MSDS because the knowledge of a corporation is beyond the realm of expert testimony. *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *23 (S.D.W. Va. Feb. 7, 2015) (evaluating the same statement in the same MSDS); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 574–75 (same) (S.D.W. Va. 2014). Accordingly, Dr. Mays cannot opine that "[i]n light of these facts," *i.e.* Dr. Mays's survey of pertinent scientific literature, "the [MSDS] for Marlex polypropylene cautions against using the material in human body" and "against exposure to strong oxidating agents." (ECF No. 30-1 at PageID #831.)

Dr. Mays also may not reference the MSDS because Plaintiff does not meet his burden to

show that the MSDSs are reliable sources for Dr. Mays to base any part of his opinion upon, as is his burden. *Nelson*, 243 F.3d at 251; *cf. In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *4 (concluding that the MSDS could not be admitted for the truth of the matter under Federal Rule of Evidence 803(18) because "Plaintiff has not established the MSDS as a reliable authority that Marlex polypropylene should not be used in permanent implants in the body"). Plaintiff simply argues that Dr. Mays relies in small part on the MSDS. (ECF No. 68 at PageID #3455.) In the event that Plaintiff calls Dr. Mays to testify, Dr. Mays may not reference the MSDSs in his testimony unless Plaintiff seeks prior permission and shows that the MSDSs are reliable sources for Dr. Mays to rely on.

4. Failure to independently validate Dr. El-Ghannam's findings

Finally, Defendants assert that Dr. Mays's opinion that oxidative degradation occurs prior to implantation in pristine meshes based on Dr. El-Ghannam's research should be excluded because Dr. Mays did not independently validate Dr. El-Ghannam's opinion. (ECF No. 30 at PageID #809.)[2] Specifically, Defendants point to Dr. El-Ghannam's Fourier Transform Infrared Spectrometry ("FTIR") analysis (ECF No. 30-1 at PageID #883), which was performed with the diffuse reflectance mode ("DRIFTS") (ECF No. 68-4 at PageID #3958, pp. 315–16). Previously, the Court held that Dr. El-Ghannam's degradation opinions, including his DRIFTS FTIR analysis of pristine meshes, are admissible. *In re Davol, Inc./ C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603389, at *6–9 (S.D. Ohio Sept. 10, 2020).[3] Even though Dr. Mays did not independently validate Dr. El-Ghannam's

[2] Defendants again argue that Dr. Mays's inclusion of the word "susceptible" renders an opinion equivocal. (ECF No. 30 at PageID #809.) Dr. Mays's opinions are not equivocal when assessed as a whole. *See supra* Part III.B.1.

[3] In Dr. Mays's expert report, he noted that the Ventralight ST polypropylene fibers peaked at 1440 cm in Dr. El-Ghannam's FTIR analysis. (ECF No. 30-1 at PageID #884.) He later testified that that "1440 cm" should have read "1740 cm." (ECF No. 68-4 at PageID #3957, pp. 311–12.)

findings, his opinions based on Dr. El-Ghannam's findings are reliable.

"Experts are permitted wide latitude in their opinions, including those opinions not based on firsthand knowledge. An expert is able to base an opinion on another expert witness for a point of expert knowledge not personally possessed." *In re E.I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) (citations omitted); *see also Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) (reviewing published studies). Thus, experts with appropriate expertise may review scientific literature and other expert reports to form their opinions. *See In re E.I. Du Pont*, 337 F. Supp. 3d at 743–44. But an expert may not simply parrot another expert's opinion. *Hutson*, 2015 WL 4040447, at *4 ("In any event, '[a]n expert must make some findings and not merely regurgitate another expert's opinion.'" (quoting *Buck*, 810 F. Supp. 2d at 844)); *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 741 & n.6 (N.D. Ohio 2014).

Dr. Mays's opinion that polypropylene fibers begin to oxidize prior to implantation is reliable. Dr. Mays is an expert in material science, specifically polymers, and Dr. El-Ghannam's opinion regarding pre-implantation degradation is well within Dr. Mays's expertise. Moreover, Dr. Mays makes many of his own findings, which are well-supported by scientific literature and his own testing and experience. For these reasons, he is more than capable of critically assessing the veracity of Dr. El-Ghannam's results—which Dr. Mays did. He compared the peak of the Ventralight ST polypropylene of Dr. El-Ghannam's FTIR analysis with his own oxidative degradation results and the results in other scientific literature. (ECF No. 68-4 at PageID #3958, pp. 316–17.) This is sufficient to convey reliability under Rule 702.

Defendants take issue with Dr. Mays's testimony that he "did not review [Dr. El-Ghannam's] report in detail" and that he "simply looked at [Dr. El-Ghannam's] experimental

results," (ECF No. 68-4 at PageID #3958, p. 316), meaning that Dr. Mays "cannot verify the reliability of [the testing] or that Dr. El-Ghannam properly followed any testing protocols," (ECF No. 30 at PageID #809.) But Defendants provide no authority that demonstrates Dr. Mays cannot verify Dr. El-Ghannam's testing based on his own expertise and his comparison of the results to his own work and a substantial body of scientific literature. Defendants' critiques of Dr. El-Ghannam's FTIR testing is best suited for cross examination of Dr. El-Ghannam, and their critique of Dr. Mays's acceptance of that type of FTIR testing is most appropriate for cross-examination of Dr. Mays.[4]

C. Impermissible topics of expert testimony

Defendants seek to exclude the section of Dr. Mays's report titled "Bard Internal Documents Regarding the Mesh Used in Their Products" because it does not address proper subjects of expert testimony. Specifically, Defendants assert that in this section Dr. Mays gives state-of-mind opinions and inappropriately summarizes events. (ECF No. 30 at PageID #803–04; ECF No. 86 at PageID #5881.) The Court concludes that Dr. Mays's report addresses improper topics, with one exception.[5]

First, Dr. Mays overtly opines that Defendants were aware of certain events or facts or

[4] Plaintiff argues that before Dr. Mays received Dr. El-Ghannam's report, Dr. Mays reached his opinion that oxidative degradation occurs in polypropylene prior to implantation. (ECF No. 68 at PageID #3457.) Defendants misinterpret this argument by construing it as one that Dr. Mays did not rely at all on Dr. El-Ghannam's FTIR results. (ECF No. 86 at PageID #5882.) But Plaintiff misinterprets the conclusions of Dr. Mays's report. It is clear that Dr. Mays did not reach a conclusion that oxidative degradation of polypropylene occurs prior to implantation without considering Dr. El-Ghannam's results.

[5] This section of Dr. Mays's report also addresses PET rings and injuries such as infection, small bowel obstruction, fistula, and cancer. (ECF No. 30-1 at PageID #871–72.) Dr. Mays's opinions regarding PET are irrelevant. *Supra* Part III.A. And opinions regarding injuries that Plaintiff does not have or for which there is no reasonable certainty he will ever develop those injuries are inadmissible. This Court previously has rejected the admission of "potential" harms without "a reasonable certainty that Mr. Johns will" suffer that harm. (ECF No. 322 at PageID #17275 (addressing cancer)); *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6604989, at *1 (S.D. Ohio Sept. 11, 2020). "[U]nless there's a manifestation of proof of a condition that's occurred, a future fear of non-cancerous conditions is excluded." (ECF No. 322 at PageID #17275.) Accordingly, Dr. Mays may not offer opinions on these topics.

possessed a certain state of mind. This is improper because an expert cannot offer an opinion on the "intent, motives or states of mind of corporations" because these opinions "have no basis in any relevant body of knowledge or expertise." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004)"); *supra* Part III.B.3. In multiple instances, Dr. Mays reviews Defendants' internal documents and infers that Defendants knew a fact or made a decision for a particular reason. (*E.g.*, No. 30-1 at PageID #867 ("Bard was well aware"), 873 ("Bard had reason to be concerned of . . . the serious inflammation issues associated with PGD"), 874 ("It thus seems that Bard's decision to add BHA to its Sepra material is to suppress this oxidative attack.").) He cannot offer these conclusions as an expert; the jury is capable of drawing their own inferences about what Defendants knew and did not know based on the internal documents without Dr. Mays's assistance. *See In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 914 (S.D. Ohio 2015) ("While a witness may testify as to facts and an expert as to opinions, only a jury may draw inferences."); *see also United States v. Kilpatrick*, 798 F.3d 365, 380 (6th Cir. 2015) ("It is not 'helpful' when a witness, lay or expert, forms conclusions for a jury that the jurors are competent to reach on their own." (quoting *Freeman*, 730 F.3d at 597)).

Second, most of this portion of Dr. Mays's report is an inadmissible historical recounting. A history without any expert analysis or other application of the expert's expertise is simply a factual narrative that "should be presented to the jury directly." *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (explaining that such expert testimony is unhelpful to the jury); *In re Rezulin*, 309 F. Supp 2d. at 551 (noting that "percipient witnesses and documentary evidence" are more appropriate venues to introduce relevant history than expert testimony). For example, the court in *In re Trasylol* concluded that an expert's summaries of emails between defendants' employees without analysis were inadmissible. 709 F.3d at 1346 &

n.30. Moreover, the court also concluded that factual summaries that suggested the defendant's motives were also inadmissible expert testimony. There, the expert opined that the defendant failed to conduct appropriate testing to obtain FDA approval for a full dose of a medication but nevertheless "slipped information into its products insert" to suggest that a full dose conferred a certain benefit. *Id.* at 1346. The court concluded that "[t]his opinion does nothing more than rely on [the defendant's] internal documents to improperly opine on [the defendant's] motive." *Id.*

In contrast, expert testimony that relies on expert knowledge and experience to contextualize, analyze, and interpret historical facts is admissible. For example, in the *In re E.I. Du Pont de Nemours & Co.* MDL, this Court concluded that it was appropriate for a corporate-conduct expert, an expert who would opine on the applicable standard of care, to "utilize[ ] his expertise and training in analytical chemistry, and his knowledge of how the state of the art methods developed over time, to contextualize the case specific facts against general developments in analytical methods." 345 F. Supp. 3d 920, 927 (S.D. Ohio 2015). And for another expert, this Court reached a similar conclusion, noting that the expert could discuss the factual record or history to help the jury assess fifty years of corporate conduct in regulatory, scientific, and technical fields to rebut the defendants' assertion that it "complied with all applicable industrial and scientific standards of care, but that it was proactive in that regard and demonstrated exemplary conduct throughout its entire history." *In re E.I. Du Pont de Nemours & Co.*, 345 F. Supp. 3d 897, 904 (S.D. Ohio 2015); *cf. In re Rezulin*, 309 F. Supp. 2d at 551 ("Likewise, the glosses that Dr. Gale interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case.").

Most of this part of Dr. Mays's report does not analyze, contextualize, or interpret pertinent factual history. The facts reported by Dr. Mays amount to quoting uncomplicated internal

documents that track the history of Defendants' acquisition and use of different brands of polypropylene resin. For instance, the first paragraphs of this section describe logistical hurdles that Defendants faced while obtaining polypropylene and how this led to switching to a different manufacturer. (ECF No. 30-1 at PageID #867–68.) This is not the complicated, technical history of a defendants' conduct beyond the understanding of the average juror as in the *Du Pont* MDL.

Even in more technical instances in this part of Dr. Mays's report, the implication is straightforward. In discussing the storage of polypropylene, Dr. Mays quotes Defendants' own testing that indicated extruded polypropylene resin "yard" should be used within nine months, but that Defendants stored the yard for more than ten years. (*Id.* at PageID #869.) The jury can reach its own conclusions regarding Defendants' conduct based on Defendants' statements without the assistance of Dr. Mays. (*See also id.* at PageID #873 (discussing other shelf-life issues that a jury would be able to understand).)

In other instances, Dr. Mays's historical summary clearly assigns a motive to Defendants. For example, Dr. Mays recounts the history of Defendants' acquisition of bioresorbable polyesters and ultimately interprets an email to conclude that "Bard continually reuses to take prompt action to properly investigate and/or resolve known or potential issues before others are harmed." (*Id.* at PageID #874.) This is impermissible.

In only one instance can the Court discern an appropriate opinion in this section of Dr. Mays's report. Dr. Mays contextualizes and refers to research explaining why Defendants' internal communications stating that the functional lifetime of the polypropylene devices is ten years or more is dubious in light of his expertise. (*Id.* at PageID #870.) He points to studies that discuss *in vivo* oxidation and how the "permanent" designation of the devices is problematic given his own study that showed oxidative degradation in polypropylene from sixteen to fifty-seven months. (*Id.*)

At the crux of the case is the reasonableness of Defendants' conduct, and Dr. Mays's expert assessment of these communications is useful to the jury.

Plaintiff counters that Dr. Mays is permitted to review Defendants' internal documents and summarize them. (ECF No. 68 at PageID #3452.) Plaintiff ignores the critical caveat, however, which is that expert testimony must assist the jury, which, as explained above, the majority of this portion of Dr. Mays's report fails to do because the jury may reach these inferences on its own. *See* Fed. R. Evid. 702(a). Moreover, "an expert may testify about his or her review of internal corporate documents *solely for the purpose of explaining the basis for his or her opinions*." *In re Davol, Inc.*, 2020 WL 6605542, at *11 (emphasis added) (quoting *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014)). But the distinction between inadmissible narration of internal documents and admissible expert testimony is the expert's actual reliance on the internal documents in forming his expert opinions. *See In re C. R. Bard, Inc.*, 2018 WL 4220602, at *4 ("[T]hough an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions."); *see also In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1368 (M.D. Ga. 2010). Plaintiff explains that this portion of Dr. Mays's report is a "review and analysis of internal documents that support and explain his conclusions, including . . . that Defendants' meshes at issue in this litigation are not suitable as permanent medical implants." (ECF No. 68 at PageID #3451.) This is far too general; Plaintiff provides no other explanation of how Dr. Mays actually relied on Defendants' internal documents to reach his opinions. Thus, Plaintiff does not meet his burden to show this part of Dr. Mays's expert report is admissible.

IV. Conclusion

Accordingly, Dr. Mays's opinions are admissible except for those related to hernia

recurrence, pain, inflammation that is unrelated to the formation of adhesions, ePTFE, PET, cancer, MSDSs, state-of-mind opinions, and historical narration without the application of his expertise. *Supra* Page 13 n.5. Thus, Defendants' motion to exclude Dr. Mays's opinions and testimony (ECF No. 30) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

6/28/2021
DATE

s/ Edmund A Sargus, JR.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE